K003745

JAN 1 6 2001

RLN Systems, Inc.

510(k) Summary

Legally marketed device(s):	K925008	RLN Systems, Inc.
	K925640	Medtronic-Xomed

Description of Device:

The Laryngeal Surface Electrode-Endotracheal Tube (LSE-ET) is a modification of the standard Laryngeal Surface Electrode (LSE) for evoked laryngeal EMG monitoring to allow it to be inserted and retained in position against the laryngeal muscles by use of an endotracheal tube. It is substantially equivalent to the standard LSE sold by RLN Systems, Inc. It is the same two-plate laryngeal electrode made of the same materials as the LSE but resized and with adhesive applied to its back surface with a paper pull-off to allow it to be attached to a standard endotracheal tube. Its electrode characteristics are equivalent to (exactly the same as) the LSE.

The LSE-ET is substantially equivalent to the Medtronic-Xomed Endotracheal Tube Electrode (ETE) in that upon attachment of the LSE-ET to a standard endotracheal tube it provides surface electrodes that are positioned in the vicinity of the laryngeal muscles for evoked EMG monitoring of the larynx. A substantial literature exists which verifies this equivalence, copies of which are found at the end of this submission.

Intended Use of the Device:

The Laryngeal Surface Electrode-Endotracheal Tube is intended to be used as a disposable, self-adhesive electrode attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures.

Technological Characteristics:

The Laryngeal Surface Electrode-Endotracheal Tube is equivalent to the predicate devices.

Biocompatibility:

Biocompatibility studies were submitted with the original LSE k925008 submission. The LSE and the LSE-ET are manufactured with the same biocompatible components.

Performance Summary:

There are no published performance standards for laryngeal electrodes. RLN Systems, Inc. and R & D Medical Products, Inc. evaluate the safety and effectiveness of the device by testing each lot of this product and by monitoring of all customer reports relating to professional use of the device.

Manufacturing:

The Laryngeal Surface Electrode, LSE-ET is manufactured by R & D Medical Products, Lake Forest, CA, according to the product specifications and under good manufacturing practices that ensure that the device is safe and effective for its intended use.

Comparison Chart for Predicate Vs Subject Devices

Comparison Item	Xomed ETE (Predicate)	RLN LSE (Predicate)	RLN LSE-ET (Subject)
Laryngeal Surface Electrode	Yes	Yes	Yes
Endolaryngeal Location	Yes	No	Yes
Postcricoid Location	No	Yes	No
Compound Action Potential 1-2 mv	Yes	Yes	Yes
One size fits all	No	Yes	Yes
Functions with all commercial EMG units	Yes	Yes	Yes
Electrode Surface	Wire	Carbon W/Ag	Carbon W/Ag

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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J. Lee Rea, M.D.
RLN Systems, Inc.
2019 Honeysuckle Lane
Jefferson City, MO 65109

Re: K003745
Trade Name: Laryngeal Surface Electrode-Endotracheal Tube, M-500-ET, LSE-ET.
Regulatory Class: II
Product Code: 77 ETN
Dated: November 28, 2000
Received: December 4, 2000

Dear Dr. Rea:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use, revised 1-3-00

The Laryngeal Surface Electrode-Endotracheal Tube is intended to be used as a disposable, self-adhesive electrode attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures. It is intended for use only by a licensed physician and in conjunction with a commercially available, medical grade electromyographic monitor.

(Division Sign-Off)
Division of Ophthalmic Dev
510(k) Number K002745